K070004

Section 5– 510(k) Summary or 510(k) Statement

I. General Information

APR 23 2007

Submitter: Alma Lasers, Ltd.
Halamish Street (PO Box 3021), Industrial Park,
Caesarea, 38900
ISRAEL

Contact Person: Tatiana Epstein
Regulatory Affairs Manager

Summary Preparation Date: April 20, 2007

II. Names

Device Names: Accent™

Primary Classification Names: Electrosurgical, Cutting & Coagulation Device & Accessories

III. Predicate Devices

- Lumenis Aluma Skin Renewal System (K051214)
- Syneron Medical Polaris WR (K031671)
- Thermage ThermaCool TC (K053365, K040135, and K033942)
- Thermage ThermaCool IIA (K013034)

IV. Product Description

The Alma Lasers Accent™ device is comprised of the following main components:

- Main console containing the major electrical components, including the:
  - Control Panel;
  - Radiofrequency (RF) Module;
  - Power Supply Module;
  - Service Panel;
  - Cooling Module;
  - Handpiece holders;
  - Emergency stop push button;
  - Key switch;
  - RF energy emission visual and audio indicators;
  - Connector ports for the handpieces and power cord;
  - Main circuit breaker; and
- UniPolar (i.e., monopolar) and Bipolar Handpieces incorporating:
  - Treatment tip with thermoelectric cooling (TEC) for cooling the treatment site during use for patient comfort;
  - Handpiece trigger;
  - Umbilical connection to the main console; and

- Accessories:
  - Cart;
  - Water Filling Kit;
  - Non-contact thermometer.

The Alma Lasers Accent™ is a portable system used to deliver radiofrequency energy to the patient treatment site via a delivery handpiece.

V. Indications for Use

The Accent™ device is intended for use in dermatologic and general surgical procedures.

The Accent™ device is indicated for use in dermatologic and general surgical procedures for the non-invasive treatment of wrinkles and rhytids using combined treatment with UniPolar and BiPolar.

VI. Rationale for Substantial Equivalence

The Alma Lasers Accent™ device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices. In addition, clinical information was provided to demonstrate safety and effectiveness.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics and clinical information provided demonstrates that the Alma Lasers Accent™ device is substantially equivalent to the predicate devices. Clinical information demonstrating the safety and effectiveness of the Alma Lasers Accent™ device for the non-invasive treatment of wrinkles and rhytids was provided.

VIII. Conclusion

The Alma Lasers Accent™ device was found to be substantially equivalent to the predicate devices.

The Alma Lasers Accent™ device shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alma Lasers, Ltd.
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Ms. Anne Worden
Regulatory Consultant
3637 Bernal Avenue
Pleasanton, California 94566

APR 23 2007

Re: K070004
Trade/Device Name: Accent™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 29, 2007
Received: April 2, 2007

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

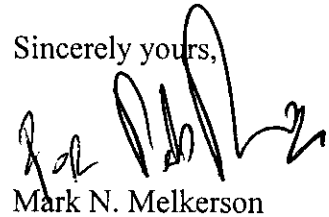
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K070004**

Device Name: **Accent™**

Indications for Use:

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The Accent™ device is indicated for use in dermatologic and general surgical procedures for the non-invasive treatment of wrinkles and rhytids using combined treatment with UniPolar and BiPolar.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070004

Prescription Use ✓	AND/OR	Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)